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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,908	12/18/2006	Amar Lulla	PAC/23361 US (4137-00700)	9899
30652 7590 08/11/2009				
CONLEY ROSE, P.C. 5601 GRANITE PARKWAY, SUITE 750 PLANO, TX 75024				
EXAMINER				
PURDY, KYLE A				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
08/11/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/576,908

**Applicant(s)**

LULLA ET AL.

**Examiner**

Kyle Purdy

**Art Unit**

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05/29/2009.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 10-16 and 18-20 is/are pending in the application.  
4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-7 and 10-16 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of t/c previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/29/2008 has been entered.

#### ***Status of Application***

2. The Examiner acknowledges receipt of the amendments filed on 05/29/2009 wherein claims 1 and 16 have been amended and claims 8, 9 and 17 have been cancelled.

3. Claims 1-7 and 10-16 are presented for examination on the merits. Claims 18-20 stand as withdrawn. The following rejections are made.

#### ***Response to Applicants' Arguments***

4. Applicants arguments filed 05/29/2009 regarding the rejection of claims 8, 9 and 17 made by the Examiner under 35 USC 102(b) over Wain et al. (WO 00/45795) have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claims.

5. Applicants arguments filed 05/29/2009 regarding the rejection of claims 8, 9 and 17 made by the Examiner under 35 USC 103(a) over Wain in view of Foldvari (PSTT, 2000) have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claims.

6. Applicants arguments filed 05/29/2009 regarding the rejection of claims 1-4, 6-7 and 11-16 made by the Examiner under 35 USC 102(b) over Wain have been fully considered but they are not found persuasive.

7. The rejection under 35 USC 102(b) is **MAINTAINED** for the reasons of record in the office action mailed on 12/01/2008.

8. In regards to the 102(b) rejection, Applicant asserts the following:

**A)** Wain does not disclose the instantly claimed limitations, i.e. at least 60% of ethanol.

9. In response to A, the Examiner respectfully disagrees. Wain does teach using 60% and even slightly more than 60% of ethanol. See page 3 and claims 3 and 18 wherein claims 3 recites using a solvent vehicle up to 90% and claim 18 limits the solvent so as to include absolute alcohol (ethanol). Thus, in at least two different situations, Wain teaches using ethanol in an amount of 60%. Applicants argument is not persuasive.

10. Applicants arguments filed 05/29/2009 regarding the rejection of claims 1-4, 6-7 and 11-16 made by the Examiner under 35 USC 103(a) over Wain in view of Foldvari have been fully considered but they are not found persuasive.

11. The rejection under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 12/01/2008.

12. In regards to the 103(a) rejection, Applicant asserts the following:

**B)** Since Wain is no longer applicable to claim 1, the obviousness rejection must be withdrawn.

13. In response to B, the Examiner respectfully disagrees. Applicant is directed to the Examiners response to A above.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**15. Claims 1-4, 6-7 and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wain et al. (WO00/45795; of record, see IDS), evidenced by STN search results.**

16. Wain et al. ('Wain) is drawn to a topical medicinal spray composition which comprises one or medicaments in a non-aqueous vehicle and one or more film forming polymers (see abstract). Example 12 discloses a sample spray formulation which comprises the pharmaceutically active agent estradiol at a concentration of 1 % w/w (see instant claims 1 and 15-17), the film forming polymers PVP-VA (i.e. polyvinylpyrrolidone-vinyl acetate copolymer, VP/VA, see STN search results) at a concentration of 4 % w/w (see instant claims 1-4), the anti-nucleating agent PVP K-30 (polyvinylpyrrolidone, see STN search results) at a concentration of 6 % w/w (see instant claims 6-8) and at least 60% of a non-aqueous vehicle. (see instant claims 1 and 13-14). It's taught that the vehicle may comprise absolute ethanol solely or in combination with other solvents. The amount of ethanol used is taught specifically to include an amount at 60%, however ethanol may be present up to 90% (see page 3 and claims 3 and 18). The composition of Example 12 also comprises polyethylene glycol 6000 and polyethylene glycol at a concentration of 2 % and 3 % w/w, respectively for a total of 5%. It is taught in the specification of Wain that polyethylene glycols are polyhydric alcohols, which in turn are skin

permeation enhancers (see page 7, 5<sup>th</sup> paragraph and page 8, 3<sup>rd</sup> paragraph; see instant claims 9 and 11).

17. Thus, the limitations of the instantly rejected claims are met entirely by Wain.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. **Claims 1-7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wain et al. (WO 00/45795; of record, see IDS) in view of Foldvari (PSTT, 2000, 3(12), 417-425).**

20. Wain is relied upon for disclosure described in the rejection of claims 1-4, 6-7 and 11-16 under 35 U.S.C. 102(b).

21. Wain fails to teach transdermal permeation enhancers as being selected from menthol, dimethylisobornide, glycerylmonooleate and myristyl lactate.

22. Foldvari is a review article drawn to non-invasive administration of drugs through the skin. It is taught that menthol (terpene) is a useful penetration enhancer which acts by disrupting intercellular lipid orders (see instant claim 10). Moreover, addition of menthol to skin increases net electrical conductivity which indicates the opening of polar pathways in the stratum corneum and allows for simplifying the passage of active agents (see Table 1, page 420).

23. Thus, one ordinarily skilled in the art, at the invention was made would be motivated to combine the teachings of Wain and Foldvari with a reasonable expectation for success in arriving at a transdermal spray formulation comprising a pharmaceutically active agent, a VP-VA copolymer, a non-aqueous vehicle, a penetration enhancer, and an anti-nucleating agent at the required weight percentages. Wain teaches a composition which comprises an active agent (estradiol), an anti-nucleating agent (PVP-k 30), a film forming polymer (PVP-VA), penetration enhancer (PEG) and non-aqueous solvents acetone (acetone, ethanol and methylene chloride). Although Wain includes penetration enhancers in their composition, Wain fails to specifically disclose using menthol as such. Foldvari et al. is a review article drawn to penetration enhancers and their use to improve transdermal delivery of pharmacologically active agents. It is specifically taught that menthol is useful as a penetration enhancer. As Wain motivates using a penetration enhancer in the composition, it follows that employing any penetration enhancer would be useful so long as it fulfills the role of performing its function. If one arrived at menthol out of the many potential enhancers and the product was successful, such a result would not be due to innovation but rather due to ordinary skill and common sense. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

### ***Conclusion***

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
August 3, 2009*

*/David J Blanchard/  
Primary Examiner, Art Unit 1643*